

1 Wherein, what is claimed is:

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3 1. A composition of matter for the transdermal administration of
4 fenoldopam comprising fenoldopam and a permeation enhancing amount of a
5 permeation enhancer in a carrier effective to permit sustained release of
6 fenoldopam at a therapeutically effective rate in order to administer a
7 therapeutically effective amount of fenoldopam in order to achieve and
8 maintain therapeutic blood or plasma levels throughout a substantial portion
9 of the administration period.

10 2. A composition according to claim 1 comprising a
11 pharmaceutically acceptable salt of fenoldopam.

12 3. A composition according to claim 2 wherein the salt is
13 fenoldopam mesylate.

14 4. A composition according to claim 3 wherein the permeation
15 enhancer comprises myristyl sarcosine.

16 5. A composition according to claim 1 wherein the permeation
17 enhancer comprises a monoglyceride.

18 6. A composition according to claim 5 further comprising a
19 cosolvent selected from the group consisting of fatty acid esters, caproyl
20 lactic acid, lauroyl lactic acid, and dimethyl lauramide.

21 7. A composition according to claim 6 wherein the monoglyceride
22 is glycerol monolaurate and the cosolvent is selected from the group
23 consisting of dodecyl acetate, lauryl lactate, isopropyl myristate, ethyl
24 palmitate, and methyl laurate.

25 8. A composition according to claim 1 comprising:

- 26 (a) 5 to 50 weight % of fenoldopam;
27 (b) 5 to 40 weight % of a permeation enhancer; and
28 (c) 30 to 90 weight % of a polymeric carrier.

29 9. A composition according to claim 8 comprising 5 to 50 weight %
30 fenoldopam base and 5 to 40 weight % of a permeation enhancer comprising
31 a monoglyceride and a fatty acid ester.

1 10. A composition according to claim 1 wherein the pH is maintained
2 below 5.5.

3 11. A composition according to claim 10 wherein the pH is
4 maintained with the range of 2 – 4.5.

5 12. A device for the transdermal administration of fenoldopam at a
6 therapeutically effective rate, comprising:

7 (a) a reservoir comprising fenoldopam and a permeation
8 enhancing amount of a permeation enhancer;

9 (b) a backing behind the body contacting-distal surface of
10 the reservoir; and

11 (c) means for maintaining the reservoir in fenoldopam
12 transmitting relation with a body surface or membrane, wherein a
13 therapeutically effective amount of fenoldopam is delivered at a
14 therapeutically effective rate during an administration period in order to
15 achieve and maintain therapeutic blood or plasma levels throughout a
16 substantial portion of the administration period.

17 13. A device according to claim 12 comprising a pharmaceutically
18 acceptable salt of fenoldopam.

19 14. A device according to claim 13 wherein the salt comprises
20 fenoldopam mesylate.

21 15. A composition according to claim 14 wherein the permeation
22 enhancer comprises myristyl sarcosine.

23 16. A device according to claim 12 wherein the permeation
24 enhancer comprises a monoglyceride.

25 17. A device according to claim 16 further comprising a cosolvent
26 selected from the group consisting of fatty acid esters, caproyl lactic acid,
27 lauroyl lactic acid, and dimethyl lauramide.

28 18. A device according to claim 17 wherein the monoglyceride is
29 glycerol monolaurate and the cosolvent is selected from the group consisting
30 of dodecyl acetate, lauryl lactate, ethyl palmitate, isopropyl myristate, and
31 methyl laurate.

32 19. A device according to claim 12 wherein the reservoir comprises:

- 1 (a) 5 to 50 weight % of fenoldopam;
2 (c) 5 - 40 weight % of a permeation enhancer; and
3 (d) 30 to 90 weight % polymeric carrier.
- 4 20. A device according to claim 19 comprising 5 to 50 weight %
5 fenoldopam base and 5 to 40 weight % of a permeation enhancer comprising
6 a monoglyceride and a fatty acid ester.
- 7 21. A device according to claim 12 wherein the reservoir comprises
8 a pressure sensitive adhesive which further acts as said means for
9 maintaining the reservoir in fenoldopam transmitting relation with a body
10 surface or membrane.
- 11 22. A method for treating an individual in need of fenoldopam
12 therapy comprising transdermally administering fenoldopam and
13 simultaneously coadministering a permeation enhancer to the individual
14 wherein a therapeutically effective amount of fenoldopam is delivered at a
15 therapeutically effective rate during an administration period in order to
16 achieve and maintain therapeutic blood or plasma levels of fenoldopam
17 throughout a substantial portion of the administration period.
- 18 23. A method according to claim 22 wherein 1 – 6 mg/day of
19 fenoldopam are administered.
- 20 24. A method according to claim 23 wherein 2 – 3 mg/day of
21 fenoldopam are administered.
- 22 25. A method according to claim 24 for the treatment of acute renal
23 failure.
- 24 26. A method according to claim 24 for the treatment of chronic
25 renal failure.
- 26 27. A method according to claim 22 wherein fenoldopam is
27 administered at a rate of 20 – 5500 $\mu\text{g/hr}$.
- 28 28. A method according to claim 27 wherein fenoldopam is
29 administered at a rate of 60 – 600 $\mu\text{g/hr}$.
- 30 29. A method according to claim 28 wherein the administration
31 period is 24 – 72 hours.

1 30. A method according to claim 22 wherein a
2 pharmaceutically acceptable salt of fenoldopam is administered.

3 31. A method according to claim 30 wherein the salt comprises
4 fenoldopam mesylate.

5 32. A method according to claim 22 wherein the permeation
6 enhancer comprises a surfactant sarcosine.

7 33. A method according to claim 32 wherein the permeation
8 enhancer comprises myristyl sarcosine.

9 34. A method according to claim 22 wherein the permeation
10 enhancer comprises a monoglyceride.

11 35. A method according to claim 34 further comprising a cosolvent
12 selected from the group consisting of fatty acid esters, caproyl lactic acid,
13 lauroyl lactic acid, and dimethyl lauramide.

14 36. A method according to claim 35 wherein the monoglyceride is
15 glycerol monolaurate and the cosolvent is selected from the group consisting
16 of dodecyl acetate, lauryl lactate, ethyl palmitate, isopropyl myristate, and
17 methyl laurate.

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